

Package leaflet: Information for the user

Melatonin Unimedic Pharma 1 mg/ml oral solution melatonin

Read all of this leaflet carefully before you or your child start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you or your child only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you or your child get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Melatonin Unimedic Pharma is and what it is used for
2. What you need to know before you or your child takes Melatonin Unimedic Pharma
3. How to take Melatonin Unimedic Pharma
4. Possible side effects
5. How to store Melatonin Unimedic Pharma
6. Contents of the pack and other information

1. What Melatonin Unimedic Pharma is and what it is used for

Melatonin Unimedic Pharma contains the active substance melatonin, which is a hormone produced naturally by the body. The hormone helps regulate the body's day- and night rhythm.

Melatonin Unimedic Pharma can be used for:

- Short-term treatment of jet lag in adults. Jet lag refers to the symptoms caused by the time difference when traveling across several time zones.
- Sleep onset insomnia in children and adolescents (6-17 years of age) with attention deficit hyperactivity disorder (ADHD) where healthy sleeping routines has not worked well enough.

2. What you need to know before you or your child takes Melatonin Unimedic Pharma

Do not take Melatonin Unimedic Pharma

- if you are allergic to melatonin or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before using Melatonin Unimedic Pharma if you or your child has:

- diabetes or impaired glucose tolerance, as this medicine may increase the level of glucose in your blood (see section 3).
- liver problems, as Melatonin Unimedic Pharma is not recommended in patients with liver problems.
- kidney problems as caution should be taken when Melatonin Unimedic Pharma is given to patients with kidney problems.
- an autoimmune disease (where the body is "attacked" by its own immune system).
- epilepsy, as melatonin might increase or decrease the frequency of seizures.

Melatonin Unimedic Pharma can make you feel drowsy. You should be careful if the drowsiness affects you, as it may impair your ability on tasks such as driving.

Children and adolescents

Do not give this medicine to children below the age of 6 years as it has not been tested and its effects are unknown.

Do not give this medicine to children or adolescents under 18 years of age to treat jet lag as its safety and efficacy are unknown for this indication.

Other medicines and Melatonin Unimedic Pharma

Tell your doctor or pharmacist if you or your child is taking, has recently taken or might take any other medicines. These medicines include:

- Fluvoxamine (used for the treatment of depression and obsessive-compulsive disorder)
- Quinolones (for example ciprofloxacin and norfloxacin) and rifampicin (used in the treatment of bacterial infections)
- Cimetidine (used in the treatment of stomach problems such as ulcers)
- Methoxypsoralens (used in the treatment of skin disorders e.g. psoriasis)
- Estrogens (used in contraceptives or hormone replacement therapy)
- Carbamazepine, phenytoin (used in the treatment of epilepsy)
- Theophylline (used in the treatment of asthma)
- Clozapine, haloperidol, olanzapine (used for the treatment of schizophrenia)
- Amitriptyline, imipramine, clomipramine (used for the treatment of depression)
- Ropivacaine (used in the treatment of acute pain)
- Tamoxifen (used in the treatment of breast cancer)
- Caffeine
- Benzodiazepines and non-benzodiazepine hypnotics such as zaleplon, zolpidem and zopiclone (used to induce sleep)
- Nifedipine
- Warfarin
- Beta-blockers (used to treat high blood pressure)
- Thioridazine (used to treat mental/mood disorders)
- Non-steroidal anti-inflammatory medicines, such as acetylsalicylic acid and ibuprofen (used in the treatment of pain and inflammation)

Smoking may reduce the effect of Melatonin Unimedic Pharma since it can increase the breakdown of melatonin by the liver. Tell your doctor if you or your child smoke, start to smoke or quit smoking during treatment.

Melatonin Unimedic Pharma with alcohol

Do not drink alcohol before, during or after taking Melatonin Unimedic Pharma, because alcohol weakens the effect of the medicine.

Pregnancy, fertility and breast-feeding

If you or your child are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before using this medicine.

Contraceptives for fertile women and young girls

Fertile women and young girls should use contraceptives under the Melatonin Unimedic Pharma treatment. Since this medicinal product may affect certain contraceptives (see “Other medicines and Melatonin Unimedic Pharma”), the choice of contraceptive should be discussed with a doctor.

Pregnancy

Melatonin Unimedic Pharma is not recommended if you or your child are pregnant. Melatonin crosses the placenta and there is insufficient information on the risk this may pose to the unborn child.

Breast-feeding

Melatonin Unimedic Pharma is not recommended if you are breast-feeding. Melatonin is passed into human breast milk, and a risk to the breast-fed child cannot be excluded.

Driving and using machines

Melatonin Unimedic Pharma may cause drowsiness. If this happens, you must not drive a vehicle, ride a bike or operate machinery.

Melatonin Unimedic Pharma contains methyl parahydroxybenzoate and sodium.

This medicine contains methyl parahydroxybenzoate which may cause allergic reactions (possibly delayed).

This medicine contains less than 1 mmol sodium (23 mg) per ml, that is to say essentially 'sodium-free'.

3. How to take Melatonin Unimedic Pharma

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Adults with jet lag

The recommended dose is 1-5 ml (equivalent to 1 to 5 mg) for a maximum of 5 days.

Recommended starting dose: 2 ml (equivalent to 2 mg)

Maximum recommended dose: 5 ml (equivalent to 5 mg) per day, for 5 days.

Take the dose at the time of bedtime at the destination, when traveling over at least 5 time zones, especially for trips in an easterly direction. The oral solution should not be taken before 20:00 hr or after 04:00 hr.

A maximum of 16 treatment cycles may occur per year.

Children and adolescents with ADHD

Recommended starting dose: 1-2 ml (equivalent to 1 to 2 mg) 30-60 minutes before bedtime.

Maximum recommended daily dose: 5 ml (equivalent to 5 mg)

The dose will be adjusted individually to a maximum of 5 ml (equivalent to 5 mg) daily, regardless of age. The lowest dose possible will be given.

Treatment should be followed up regularly by a doctor (at least every 6 months is recommended) to see if it is still appropriate. Treatment should be interrupted once a year to see if treatment is still needed.

Method of administration

Melatonin Unimedic Pharma should be swallowed.

Instruction for use

1. Open the bottle by removing the bottle cap.
2. Insert the syringe into the hole of the integrated adapter in the bottle opening and turn the bottle upside down. Measure the volume the doctor has prescribed by slowly pulling out the plunger. Read the dose on the top of the piston. Turn the bottle right and remove the syringe.
3. You or the child should sit upright when receiving Melatonin Unimedic Pharma. Aim the tip of the syringe at the inside of the cheek. Slowly push in the plunger and allow the child to swallow naturally. Too fast administration of the medicine into the throat can cause discomfort.
4. Clean the inside of the syringe after each use.

Diabetes

If you have or your child has diabetes or impaired glucose tolerance, food should not be consumed 2 hours before or 2 hours after intake of Melatonin Unimedic Pharma, see Warnings and precautions.

If you or your child takes more Melatonin Unimedic Pharma than you/they should

If you or your child has accidentally taken too much medicine, or if for example a child has ingested the medicine by mistake, contact a doctor or pharmacist as soon as possible.

Taking more than the recommended daily dose can make that you or your child feels drowsy.

If you or your child forgets to take Melatonin Unimedic Pharma

If you or your child forgets to take a dose and wake during the night you may take the forgotten dose but at no later than 04:00 in the morning

Do not take a double dose to make up for a forgotten dose.

If you or your child stops taking Melatonin Unimedic Pharma

There are no known harmful effects if treatment is interrupted or ended. The use of Melatonin Unimedic Pharma is not known to cause any withdrawal effects after treatment completion.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you, or your child, experience any of the following serious side effects, tell your doctor immediately and stop taking the medicine.

Frequency not known:

- Hypersensitivity reaction, (allergy like reactions such as itching, difficulties to breath).
- Swelling of deeper layers of skin (angioedema)
- Swelling in mouth and tongue (oedema)

Other side effects that might occur are listed below.

Common: may affect up to 1 in 10 people

- Headache
- Sleepiness

Uncommon: may affect up to 1 in 100 people

- Irritation, nervousness, restlessness,
- Sleeplessness (insomnia), abnormal dreams, nightmares, night sweats, anxiety, anxious restlessness, physical weakness, lack of energy and enthusiasm,
- Migraine
- Dizziness
- High blood pressure
- Mouth ulceration
- Dry mouth
- Nausea, abdominal pain
- Skin disorders (dermatitis, pruritus, rash, dry skin)
- Pain in arms and legs
- Menopausal symptoms
- Chest pain
- Excretion of glucose in the urine, excess proteins in the urine

- Changes in the composition of your blood which can cause yellowing of the skin and eyes
- Abnormal liver function tests
- Increased weight

Rare: may affect up to 1 in 1,000 people

- Shingles (herpes zoster)
- Reduced number of white blood cells in the blood
- Reduced number of blood platelets
- Low calcium or sodium levels in the blood
- High level of blood fats
- Changes in mood, aggression, agitation, crying, stress symptoms, feeling confused (disorientation), early morning awakening, increased sex drive (increased libido), depressed mood, depression
- Fainting, memory impairment, disturbance in attention, dreamy state, uncomfortable sensation in legs (restless legs syndrome), poor quality sleep, tiredness (fatigue)
- Visual impairment, blurred vision, increased tearing
- A feeling of dizziness or spinning (Vertigo), dizziness when standing or sitting
- Faster heartbeats, chest pain due to angina pectoris
- Acid reflux, gastrointestinal disorder, blistering in the mouth, tongue ulceration, stomach upset, vomiting, abnormal bowel sounds, increased salivation, bad breath, flatulence, abdominal discomfort, inflammation of the stomach lining
- Abnormal dermal sensation (paresthesia), skin disorders (eczema, erythema, psoriasis, rash), nail disorder, sudden feeling of heat (hot flush)
- Pain, arthritis, muscle spasms, neck pain, night cramps,
- Passing large volumes of urine, presence of red blood cells in the urine, need to urinate at night
- Prolonged erection (priapism)
- Inflammation or swelling of prostate gland (prostatitis)
- Thirst
- Increased liver enzymes, abnormal blood electrolytes and abnormal laboratory tests

Not known (reported from use in adults)

- Spontaneous flow of milk from the chest

Additional side effects in children and adolescents

A low frequency of generally mild side effects has been reported. The most common adverse effects were headache, hyperactivity, a feeling of dizziness or “spinning” (vertigo) and abdominal pain. No serious adverse effects have been observed.

Reporting of side effects

If you or your child get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system listed in Appendix V](#).* By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Melatonin Unimedic Pharma

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the bottle after EXP. The expiry date refers to the last day of that month.

Melatonin Unimedic Pharma can be used up to 6 months after first opening of the bottle.

Do not store above 30°C. Store in the original bottle in order to protect from light.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Melatonin Unimedic Pharma contains

- The active substance is melatonin
- The other ingredients are glycerol (E422), sorbic acid, methyl parahydroxybenzoate (E218), sodium hydroxide (for pH adjustments) and purified water.

What Melatonin Unimedic Pharma looks like and contents of the pack

Melatonin Unimedic Pharma is a clear colorless to yellow oral solution.

Solution in an amber glass bottle with a child-resistant white polypropylene/polyethylene cap with an integrated syringe adapter (30 ml, 100 ml and 150 ml). An oral syringe is packed together with the bottle. The capacity of the syringe is 5 ml with scale graduation of 0.2 ml.

Pack size: 1 x 30 ml, 1 x 100 ml, 1 x 150 ml

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

To be completed nationally

This medicine is authorised in the Member States of the European Economic Area under the following names:

Belgium:	Melatonin Unimedic Pharma
Denmark:	Melatonin Unimedic Pharma
Finland:	Melatonin Unimedic Pharma 1 mg/ml oraalliuos
France:	APHELYS 1 mg/mL, solution buvable
Germany:	Melatonin Unimedic Pharma 1 mg/ml Lösung zum Einnehmen
Norway:	Melatonin Unimedic Pharma 1 mg/ml mikstur, oppløsning
Sweden:	Melatonin Unimedic Pharma 1 mg/ml oral lösning

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